U.S. Food and Drug Administration

DRAFT GUIDANCE

CUSTOM DEVICES

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For further information, contact _____.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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GUIDANCE FOR INDUSTRY

Custom Devices

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I. INTRODUCTION

This draft guidance concerns Section 520(b) of the Federal Food, Drug, and Cosmetic Act (the Act) which governs custom devices. Custom devices are devices that deviate from an approved premarket application (PMA) or cleared 510(k), and are manufactured in response to a specific request from a physician or dentist. This guidance document describes how a device might meet the statutory requirements in Section 520(b) and be considered a custom device under the Act.

II. BACKGROUND

Statutory Background.

Section 520(b) of the Act, 21 USC 360j(b), allows the manufacture and introduction into interstate commerce of custom devices. Custom devices are devices that, in order to comply with an order of a physician or dentist, necessarily deviate from an otherwise applicable performance standard or PMA requirement of the Act, if certain conditions are met. Under Section 520(b), custom devices are exempt from the requirements in Sections 514 and 515 of the Act, and by regulation are exempt from the 510(k) procedure (21 CFR 807.85) and from IDE procedures (21 CFR 812.2(c)(7)).

In enacting Section 520(b), Congress recognized that physicians had a need for custom-made devices for specific patients or for specific aspects of physician practices. Congress was aware of the practice of creating devices for unusual needs of patients and health care practitioners, and intended to create a statutory provision that would allow a limited number of custom devices to be produced for these cases. Congress also intended that the use of custom devices not become a regular course of conduct. Custom devices were not to be used repeatedly in a way that would be, in effect, an unsupervised, unregulated clinical trial.

Statutory Requirements.

Under Section 520(b), a device is considered a "custom device" if:

1. The device is

   - not generally available in finished form for purchase or for dispensing on a prescription, and

   - not offered through labeling or advertising for commercial distribution, and

2. The device is intended

- for use by an individual patient named in the prescription and is to be made in a specific form by such patient, or

- to meet the special needs of a physician or dentist or other health care professional in his practice, and

3. The device is not generally available to or generally used by other practitioners.

If the requirements of Section 520(b) are not met, the device is considered adulterated and misbranded and will be subject to an enforcement action.

Definitions in Section 520(b).

Necessarily Deviates - means that the device cannot be manufactured following the current statutory and regulatory requirements in order to meet the needs of the requesting physician or health practitioner, i.e., the device would not be covered by an existing approval or clearance.

Not generally available for commercial distribution - means that the device is not available for purchase or use through another legal means, i.e., it is not marketed by any source, nor is it the subject of a clinical trial.

Not generally available - means that the use of the custom device has not become a regular course of conduct in the health care community.

Individually named patient– means a specific patient whose name is provided to the manufacturer. It cannot be a general class of patients or an expected patient.

Special needs – means that a health care practitioner needs a device to use in his or her practice because of physical need or other environmental constraint in the practice, e.g., a scalpel or glove for a physician with a hand deformity or a requirement unique to a medical facility that precludes the use of generally available devices.

What is a Custom Device?

The proposed use of the custom device must satisfy the requirements of Section 520(b). For example, the following categories of devices could be considered custom devices:

- allergy – a patient may be allergic to a material in a device and the manufacturer may be asked to replace the material or cover it. If this practice develops into a regular course of conduct, you should consult Office of Compliance and Office of Device Evaluation about whether a PMA or 510(k) would be required.

- unusual size -- a device may be cleared/approved for a range of sizes that are expected to cover the whole patient population. When a patient of an unusual size presents to the doctor, it may be appropriate to create a custom device for that patient.

- physical limitation of doctor – a physician with missing fingers, for example, may need special instruments made as custom devices.

- limitation or requirement of health care facility – an institution that has specific environmental, space, or practice constraints may require a device to be modified for its use at that facility.

On the other hand, the following categories would not be considered custom devices:

- a device intended to be used in a clinical trial

- a device intended to be used to test a company's new product idea

- a device intended to be used to test a health care practitioner's new product idea.

Devices that are used in a wide range of sizes are not custom devices simply because the physician prescribes a specific size for a patient. For example, contact lenses or aortic abdominal aneurysm (AAA) stents are prescribed to fit each patient, but these are not considered custom devices. The individual prescriptions are a part of the intended use of the device and are covered in the approval or clearance obtained for the product.

Similarly, devices that are designed to be modified by the health care professional to fit patients may not necessarily be custom devices. For example, dentures are often adapted by the dentist to fit the patient, but this does not make them custom devices. Such devices should be approved/cleared in a manner which recognizes the need for later modification. The scope of the approval/clearance should cover the range of modifications to be performed by the health care professional.

III. QUESTIONS AND ANSWERS

1. **Q. How many custom devices can I make?**

   A: The number of a particular custom device that can be made varies with the type of device, the intended use, and the needs of the patients. For every custom device made, whether it is the first, second or ninth, the intended use may be different, and therefore you must determine that each custom device fulfills the requirements of the Act. For example, there are some devices, such as gloves for a particular physician, that can be manufactured several times in larger lots for continued use by that physician, but this is not necessarily true for all devices.

For an implantable device, it may be appropriate only to distribute a dozen per year.

If your device meets the criteria in Section 520(b), the Office of Compliance generally will not take an enforcement action if you are producing ten or fewer of a device per year. Of course, any one device could be adulterated and misbranded if it no longer meets the requirements in Section 520(b).

If you manufacture enough of a particular device to conduct a valid feasibility study, FDA advises that you contact the agency to determine whether your device is a custom device, or whether you should conduct a clinical study in compliance with the Act and regulations.

2. **Q. Do I need FDA approval before I distribute a custom device?**

   A: No. There is no approval or notification requirement for custom devices. However, manufacturers are urged to communicate with the Office of Device Evaluation and the Office of Compliance to be sure the most appropriate legal means are being used to distribute the requested device.

3. **Q: What do I do if requests for my custom device increase, but yet the low demand for the device still makes it impractical to apply for an HDE, much less a PMA?**

   A: Consult with the Office of Compliance and your reviewing division in the Office of Device Evaluation. There are other ways to legally provide your device, using the Compassionate Use and Emergency Use procedures, for example. You may also be able to obtain a 510(k) or PMA with very specific labeling for a narrow intended use to cover the specific needs of the patient or patient class.

4. **Q: Can we fulfill a doctor's request for an instrument to use in his or her practice on a whole class of patients?**

   A: Possibly, as long as the device meets the requirements of section 520(b). If the request is based on a unique situation in the doctor's practice and the situation is not found in other practices, the device may qualify as a custom device. You should consult with the Office of Compliance to determine whether the device would be considered a custom device.

5. **Q: Can a device approved in another country be a custom device in the United States?**

   A: Yes, if all the requirements of 520(b) are met. However, if you intend to seek approval for the device in the U.S., the device should be the subject of a clinical trial. If a clinical trial is ongoing or planned in the U.S., it is not a custom device.

The manufacturer should analyze the issue in the same manner as any other custom device request and make a determination of whether the request satisfies the statutory criteria.

6. **Q: Can a modification of a marketed device be a custom device?**

   A: Yes, if all the requirements of 520(b) are met. Custom devices are often variations of existing devices. One example could be a marketed device that a physician wants to use in a different organ in the body or for a different indication that would require modification of the device.

7. **Q: What if the physician asks for a modification of an investigational device?**

   A: An investigational device cannot be a custom device for use in the indication being studied in the clinical trial. However, if a physician asks for a custom device which can be made by modifying an investigational device, the same analysis must apply: If the request satisfies the statutory criteria of 520(b), the product may qualify as a custom device. You should discuss this with Office of Compliance and Office of Device Evaluation, since it may be more appropriate to provide this product to the requester using a different method, such as a Compassionate Use, by means of a supplement to the IDE.

8. **Q: Does the manufacturer have to know the name of the patient?**

   A: Yes, section 520(b) requires that the patient be named.

9. **Q: Does requesting the patient's name raise privacy issues, such as those in the HIPAA regulations?**

   A: It is important to protect the privacy of patients. However, the HIPAA regulations allow transfer of protected health information for some uses. Make sure all privacy regulations are followed.

10. **Q: Does the Quality System Regulation apply to Custom Devices?**

    A: Yes. Section 520(b) does not exempt custom devices from GMP/QSR. The QSR provides flexibility for various types of devices, so you have to determine, for each device, how to satisfy the QSR. For example, the provisions of the QSR that concern repeatable production of a device may not be relevant to a custom device, because only a small number of the custom device will be produced. There also may be no formal production documents, such as manufacturing travelers, for the custom device because it will be produced on an individual basis. Additionally, provisions concerning the design control process may not be relevant, because the person requesting the custom device typically provides the design inputs. Finally, design validation may not be possible for production of a single device or a small number of devices. Should you produce a greater number

of a particular custom device, then it may be necessary to develop systematic procedures under the QSR. In each case, the manufacturer must determine how to best protect patient safety by appropriately complying with the QSR.

11. Q: Do we have to file Medical Device Reports (MDRs) on a custom device?

A: No, as long as it is truly a custom device. The purpose of MDR reporting is for trending of performance of marketed devices, and a true custom device will only be prescribed for one patient or a small number of patients. Therefore, the policy behind trending performance is not applicable.

However, be aware that if the custom device is a modification of an approved/cleared device, you should consider whether an MDR-reportable event associated with the custom device is relevant to performance analysis of the original device. In such a case, an MDR on the original device may be appropriate.

12. Q: Who are the contact people in CDRH to answer questions?

In Office of Device Evaluation, the following people may be contacted: _____, phone 301-594-____.

In Office of Compliance, the following people may be contacted:

_____, phone 301-594-____.